Case Number:	CM13-0058692		
Date Assigned:	12/30/2013	**Date of Injury:**	01/04/2011
Decision Date:	05/07/2014	**UR Denial Date:**	10/25/2013
Priority:	Standard	**Application Received:**	11/27/2013

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Physical Medicine and Rehabilitation, has a subspecialty in Pain Management and is licensed to practice in Texas and Oklahoma. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The injured worker is a 52-year-old female who reported injury on 01/04/2005. The mechanism of injury was noted to be the injured worker was carrying a 2-year-old child out to the pool area and the child started to squirm while the injured worker was standing on a mat. The mat moved due to the ground being wet from rain water and as the mat moved the injured worker lost her balance, twisted her body and her left ankle in order to keep the child from falling. The documentation of 10/01/2013 revealed the injured worker had tenderness to palpation over the lateral joint line of the left ankle. The diagnoses included left ankle lateral malleolus fracture, chondromalacia patella, low back syndrome, left ankle osteoarthritis, and joint pain along with left knee osteoarthritis and degenerative joint disease. The request was made for tramadol, TG hot and Fluriflex, and Lidoderm patches.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

TRAMADOL 150MG #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol/Ongoing Management Section Page(s): 78, 82, 93, 94 and 113.

Decision rationale: The California MTUS states Central analgesics drugs such as Tramadol (UltramÂ®) are reported to be effective in managing neuropathic pain and it is not recommended as a first-line oral analgesic. There should be documentation of an objective improve ment in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to provide the duration the injured worker had been on the medication and the frequency for the medication. There is a lack of documentation indicating the necessity for both a topical and an oral form of tramadol. Given the above, the request for tramadol 150 mg #30 is not medically necessary.

TOPICAL CREAM: TGHOT AND FLURFLEX 180 GRAMS: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol/Gabapentin/Topical Capsaicin/Topical Analgesics/Topical Salicylates/ Flurbiprofen/ Cycl. Decision based on Non-MTUS Citation FDA.gov.

Decision rationale: The California MTUS indicated that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety... are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed...Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended....Topical Salicylates are recommended... A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The approved form of Tramadol is for oral consumption, which is not recommended as a first line therapy...Gabapentin: Not recommended. There is no peer-reviewed literature to support use... Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There have been no studies of a 0.0375% formulation of capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. California MTUS guidelines recommend Topical Salicylates. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound and it is not certified. The clinical documentation submitted for review failed to provide documentation that the injured worker had neuropathic pain and had trialed and failed antidepressants and anticonvulsants. There was a lack of documentation indicating exceptional factors to warrant non-adherence to guideline recommendations. Additionally, there was a lack of documentation indicating the necessity for an oral and topical form of tramadol. Given the above, the request for TG hot would not be supported. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. This agent is not currently FDA approved for a topical application. FDA approved routes of administration for Flurbiprofen include oral tablets and ophthalmologic solution. A search of the National Library of Medicine - National Institute of Health (NLM-NIH) database demonstrated no high quality human studies evaluating the safety and efficacy of this medication through dermal patches or topical administration... California MTUS Guidelines do not recommend the topical use of

Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. The addition of Cyclobenzaprine to other agents is not recommended. The clinical documentation submitted for review failed to provide the duration for this requested medication. There was a lack of documentation indicating the injured worker had neuropathic pain and that there had been a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the duration and frequency as well as the strength of the requested cream. Given the above, the request for topical cream TG hot and Fluriflex 180 grams is not medically necessary.

LIDODERM PATCHES #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines LIDODERM Page(s): 56-57.

Decision rationale: The California MTUS guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). The clinical documentation submitted for review failed to provide the duration the injured worker had been on the medication. There was a lack of documentation indicating the injured worker had trialed and failed a first line oral therapy. The request as submitted failed to provide the duration, strength and frequency for the Lidoderm patches. Given the above, the request for Lidoderm patches #30 is not medically necessary.